Comments and Recommendations from SQO Scientific Steering Committee
July 14, 2010

All SQO SSC members were present for the July 13 presentations and updates from members of the Science Team (Bay and Greenfield). The SSC met on July 14 to discuss the findings and develop recommendations for future Science Team activities. Discussion focused on 8 major topic areas:

1. Timing and review of work products
    a. Document review needs
    b. Mechanism of SSC-Science Team interactions
2. Assessment framework
    a. Is it adequate for SQO program?
    b. What modifications are needed?
3. Data quality issues
    a. Methods (e.g., PCB Congeners)
    b. Minimum data requirements
    c. Reporting Limits
    d. Use of nondetects
    e. Chemical summing rules
4. Data use and analysis
    a. Combining consumption rate data from different studies
    b. BAFs (fish concentration wet weight divided by sediment concentration dry weight) across all species or by guilds?
    c. Which statistics?
    d. Use all data or all means for tissue chemistry data analyses?
5. Assessment scale
    a. How to assess hot spots whose influence may disappear with application of site use factors?
6. Tier III
    a. Define what Tier III is and when it is to be applied
7. Tier I
    a. Data requirements
    b. Decision rules
8. Use of other data types
    a. Aid in interpretation of sediment contribution results

Comments by topic area:

1. Timing and review of work products

There is a need for SSC to review three primary documents relating to indirect effects assessment:

a) Assessment framework description
b) Bioaccumulation model description
c) Sampling/study design guidance

In addition, the Water Board would appreciate comments on indirect effects program implementation guidance; recognizing that policy considerations rather than technical factors may determine the final guidance.

Ongoing efforts by the Science Team to develop tools and recommendations for direct effects assessment in estuaries (e.g., Sacramento and San Joaquin River Delta) will also result in several documents for SSC review and comment.

The SSC concluded that it was unrealistic for the Science Team to complete all draft documents sooner than six months; additional time would be required for the SSC to review them and provide comments. The Water Board should extend the program schedule to allow sufficient time for the Science Team to complete its work. The SSC also directed the Science Team to provide them with a schedule of future products and delivery dates for use in planning review/meetings.

Chris Beegan commented that he expects to have a draft staff report completed by June 2011, so that a six-month window would be feasible.

Discussion regarding the timing and mechanism of future interactions between the SSC and Science Team resulted in identifying several strategies and action items:

- An internet wiki site will be set up to facilitate SSC review, comment, and revisions on interim Science Team work products. Brock Bernstein and Steve Bay will set up the site.
- Conference calls will be scheduled as needed to develop consensus recommendations/approve documents.
- It is impractical to have another SSC meeting before December 2010. As an alternative, a two-hour SSC meeting with the Science Team will be scheduled during the November 2010 SETAC meeting to work on remaining issues for the indirect effects program.
- A tentative meeting date for the next SSC meeting at SCCWRP will be scheduled once a timeline of work deliverables has been provided by the Science Team. This meeting will focus on the direct effects tools for estuaries.

Among the documents to be reviewed by the SSC, one of the documents should contain the model, the conditions that have been selected to run the model for Tiers I and II, and the justification for any parameter selection and assumptions that are made for modeling activities. The method(s) used to fit data to statistical distributions and the ultimate choice of statistical distribution type (e.g., normal, lognormal) also should be justified and documented. For example, uncertainty about the arithmetic mean chemical concentration may follow a normal distribution given the Central Limit Theorem. Given how critical this model is to Tier II, we need to be sure it is sufficiently generalizable so it doesn't need to be calibrated & validated differently at each & every site (if this were the case it would be too unwieldy to use). In Appendix B, which of the variables are user defined and which are pre-determined? In addition to the dietary matrix, diagrams of the feeding relationships would be helpful for explanatory purposes.

2. Assessment framework

The overall construct of the assessment framework is appropriate for addressing the SQO indirect effects assessment questions with respect to PCBs and chlorinated pesticides. While it is intended that the framework be applicable in the future to other contaminants (e.g., dioxins, Hg),

such applications will likely require the use of substantially different data analysis tools and/or models. For example, for metal contaminants like mercury and selenium, new bioaccumulation models will need to be developed. However, the current bioaccumulation model is satisfactory for addressing other nonionic organic contaminants (e.g., dioxin, furans) assuming the input data are available for the model to operate. It was recommended that the Water Board specify the future intentions with regard to expanding the scope of the indirect effects assessment framework. Clarification is also needed regarding the scope of the assessment with regard to issues such as sediment depth and time frame to ensure that the framework is suitable to such conditions as buried sediments. The depth issue may be very important given the newly adopted policy pertains to quality/toxicity, etc. of the top 5cm of sediment only (likely to be highly mobile at many sites).

The SQO framework for indirect effects is a departure from other programs in that sediment concentrations will not drive impacts without evidence of unacceptable tissue contamination.

The SSC emphasized the standardized components of framework (i.e., Tiers I and II) have value and that the data analyses or implementation guidance should not drive everything to requiring use of Tier III. The calculation of the sediment contribution value in Tier II is only the start of an allocation based process to address sources/management.

The purpose of Tier III is different and would involve more extensive assessment to determine the characteristics of the site. There should be a clear description of the purpose for each tier and clear distinctions among them.

The SSC recommended that the Water Board's policy include guidance regarding when to use Tier III and what are its components/applications. The SSC should probably spend more time discussing Tier III once the Water Board's guidance is more clearly defined.

Discussion of the table for integration of consumption risk and sediment contribution results (Table 3 in stochastic assessment approach document) focused on the management implications of the final site assessment category names (e.g., unimpacted, likely impacted). SSC members recommended the category names be dropped in favor of using narrative descriptions to represent the final assessment results. Use of the proposed category names suggests specific management responses which may be inappropriate for some programs or site-specific situations. However, further discussion during the public portion of the meeting, suggested that the advisory committee would like to have some terminal description. Thus, it would be appropriate to examine terms. For instance, there are 16 rows in Table 3. Rows 1-9 and 13 could be "Management Action Not Indicated", while Rows 11-12 and 15-16 could be "Management Action Indicated", and rows 10 and 14 could indicated a requirement for a tier III assessment. It is likely that if management action is required a Tier III assessment would be performed. Thus, these terms would be useful to the regulatory process but would not drive specific management decisions. The science team was directed to find new terms that would be of some value.

SSC members also pointed out that category results for consumption risk and sediment contribution could vary depending on the conceptual model and parameters used (e.g., consumption rate, target population). Wording of the narrative assessment statements should be compatible with different types of conceptual models for the assessment. As a caution, relying on narratives alone may result in many different narratives for the same row (to cover many site-specific conditions).

3. Data quality issues:

Not discussed in detail by the SSC. This is a very important issue and should be reviewed by the SSC once a protocol is in place from the Science Team.

4. Data use and analysis

The SSC is concerned that the proposed methods of aggregating fish concentration data will lead to inaccurate results as species-specific traits and consumption patterns are not explicitly incorporated into the modeling and analysis methods. Use of composites to represent tissue contamination in site fish may also lead to an underestimation of consumption risk as extreme values in individual fish may not be represented in the data distribution. If compositng is to be used, a sound rationale for compositing must be developed given the implications this will have on estimating variability and uncertainty.

A fish guild-based approach should be used for the bioaccumulation modeling to determine the site sediment contribution percentage and calculate consumption risk. A schematic depiction of the components of this approach is presented in Figure 1. To implement this approach, several elements must be developed by the Science Team:

1. Several fish guilds (e.g., 3-4) must be identified that reflect the major life history and food-web characteristics of resident seafood consumed by fishers. Selection of fish species for representative food webs and guilds requires work and specific guidance within the effort.
2. A bioaccumulation model should be developed to represent each guild. This model should represent the actual characteristics of a typical species for the guild.
3. Separate model runs are conducted for each guild that is relevant to the specific site being assessed; the results are used to calculate the percent sediment contribution for each guild
4. The individual guild results are integrated to determine the overall sediment contribution value by combining the results in proportion to actual consumption patterns; a methodology and values for conducting the integration should be developed by the Science Team.

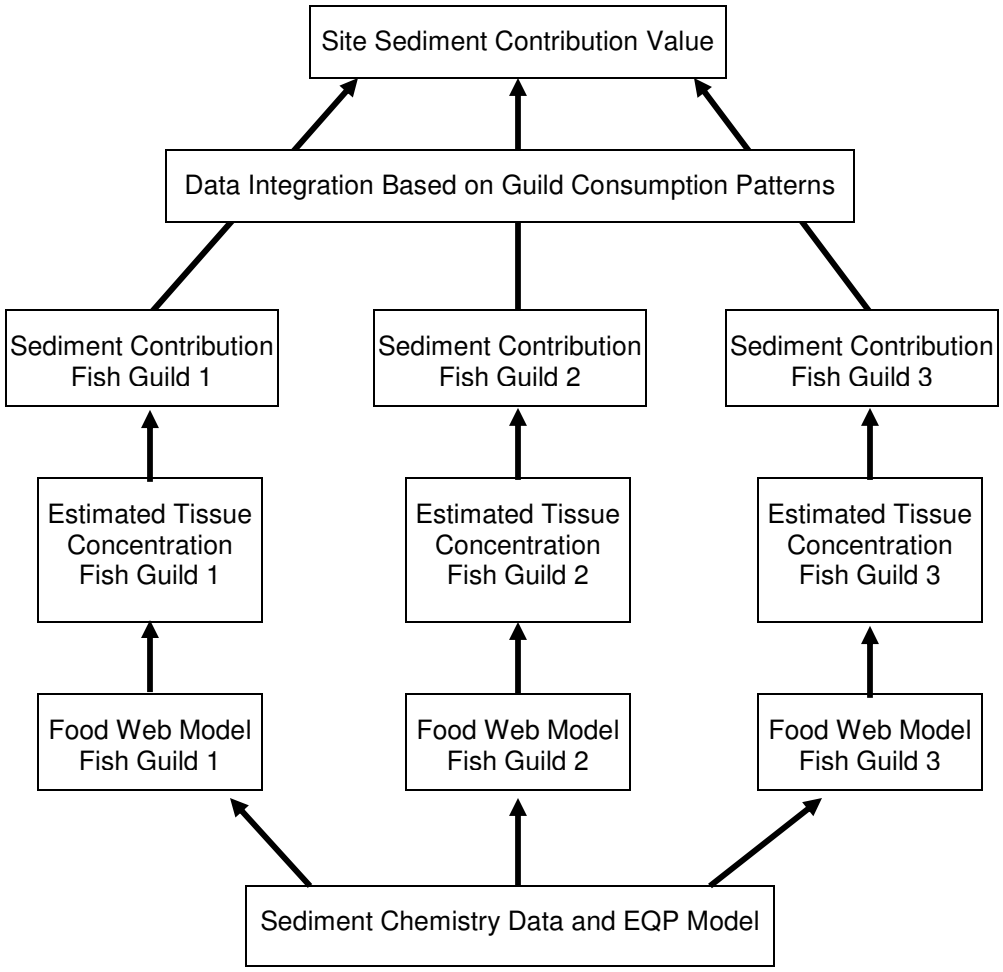

Figure 1. Strategy for determining the site sediment contribution to fish bioaccumulation. The number of guilds included in the analysis depends of the site conceptual model.

5. Assessment scale

The choice of the site boundaries and area is an important part of developing the assessment study design and guidance needs to be developed to guide such decisions. The assessment framework utilizes a site use factor in the determination of the percent sediment contribution value, which is currently calculated from the site area and forage area of the seafood. Theoretically, application of such a framework at very small sites could result in a situation where even sites with extremely high levels of contamination could meet the SQO due to use of a very small site use factor. Conversely, applying the site-level assessment to a large area where the contamination varies markedly along a gradient may result in the failure to identify subregions of the site where the sediments pose a significant risk to human health. There is a related concern that selection of a standardized target population or consumption rate may not be appropriate for all assessment situations. Due to the diversity of applications expected for the indirect effects assessment framework, it is not feasible to prescribe a simple approach to address such scale issues that will work in all cases.

The SSC recommends that a problem formulation step be required before conducting any of the Tiered assessments. This step would include development a site conceptual model and include consideration of the assessment site boundaries, a map of the site, site use factor, target

population, and consumption rate. This conceptual model should then be used to develop the site sampling and analysis plan, which might include modifications to key parameters such as site use factor, fish guilds used for assessment, and consumption rate. The site assessment study design should be integrated with a regional management plan for the water body so that the study design appropriately considers factors such as spatial patterns in land use/contamination, contaminant sources, temporal patterns, and other assessment activities. As a caution, Tier I was intended to be a fairly simple direct approach and thus requirements for an extensive conceptual model may be excessive. Thus, the extent of the expected conceptual model should be provided in the guidance for Tier I.

Further, if additional information is to be used to inform management decisions after the Tier II or III assessment, it would be good to disclose or discuss as much of that information as possible, prior to application of the tiers (i.e., during problem formulation). This would lessen the perception that this new information conveniently appeared just in time to influence management's thinking.

6. Tier III

The Water board should develop guidance that clarifies the distinction between Tier II and Tier III assessments. Such guidance should include information to aid the user in deciding when a Tier III assessment in warranted. The SSC identified several situations indicative of the need for Tier III:

- Substantial disagreement in consumption risk and sediment contribution results
- Evidence of other sources or spatial scale issues
- Need to improve robustness of assessment for sites of high concern/contention
- Different or more detailed analyses needed in order to determine if likely risk to human health is acceptable/unacceptable
- Desire to incorporate additional site-specific information into the assessment

7. Tier I

The decision rules for interpreting the Tier I sediment and tissue analysis results were reviewed. Because there is an option for the Tier I assessment to result in a finding that the site meets the SQO, it is imperative that the data used to make the assessment meet minimum standards of quality and representativeness. The Science Team should provide guidance regarding data quality standards. It is also assumed that the Tier I assessment method will use parameters that will result in a more conservative outcome in order to reduce the likelihood of false negatives resulting from the use of limited data. To include the most accurate and relatively low-cost collected data, a framework should be suggested to users for future data collections to use actual seafood lipid content rather than a conservative estimate. For existing datasets where local lipid data are unavailable, use a conservative estimate. The SSC recommends that if results from either the sediment or tissue analyses indicate a potential to exceed the human health risk threshold, then a Tier II analysis is warranted. While this recommendation is contrary to the original concept developed by the SSC, it is consistent with other assessment programs and represents prudence with respect to protecting water quality and human health. Based on this recommendation the SSC developed a revised table of outcomes for various Tier I results combinations (Table 1). Evaluation of both types of data in Tier I is recommended by the SSC.

Table 1. Assessment outcomes of the Tier I framework. NA = data type not available/no results

Sediment Result	Seafood Result	Tier I Outcome
Below threshold	NA	Meets SQO
Above threshold	NA	Proceed to Tier II
NA	Below threshold	Meets SQO
NA	Above threshold	Proceed to Tier II
Below threshold	Below threshold	Meets SQO
Below threshold	Above threshold	Proceed to Tier II
Above threshold	Below threshold	Proceed to Tier II
Above threshold	Above threshold	Proceed to Tier II

Tom Gries had some additional thoughts on the table that were not discussed by the SSC but should be addressed at some point.

Row 1: Should a site lacking any tissue data really be off the hook? Wouldn't you want to at least post a sign saying health risk to humans via consuming fish caught in this area has not been evaluated (hence, actionable)?

Row 3: What if a site has screaming hot sediment concentrations but low actual measured tissue chemistry (either low bioavailability at site or site use factor very limited/small). Meets SQO for **indirect** effects but perhaps not for direct effects. Even if meets SQO for direct effects, may be a good idea to examine bioavailability with bioaccum. tests or other approach.

8. Use of other data types

There are often other types of data available for the site that are not included in the Tier I or Tier II assessment methods. Such data often contain information that could improve the interpretation of the indirect effects SQO and the Water Board should include guidance pertaining to the use of such data in the assessment process. For example, the results of the direct effects assessment should be considered before final management decisions regarding the site as a whole are made. These other data types can also be helpful in interpreting the results of the sediment contribution analysis, determining the need for a revised assessment study design, or deciding whether to conduct a Tier III assessment. Examples of other data types of particular use include:

- Baseline sediment contamination data (e.g., outside of site being assessed)
- Presence of spatial gradients in sediment contamination
- Laboratory bioaccumulation test results

The SSC did not have sufficient time to discuss the alternative proposal forwarded by the Advisory Committee to incorporate Monte Carlo simulation results into the contaminated sediments contribution line of evidence.

Additional comments:

Several SSC members provided additional comments on specific aspects of the SQO program that were not discussed in detail by the SSC. These comments are provided below for consideration and response by the Science Team.

Team should look for ways to find common ground in approach for addressing human health impacts and risks to fish and wildlife. The exposure modeling part of the problem should be compatible with both purposes. This will help address funding constraints and will position the State to expedite consideration of fish and wildlife impacts when it has the resources to do so.

The fact that the State's approach does not address inland rivers, streams, or reservoirs is a problematic gap that should be considered by the state.

There needs to be technical coherence between the approach and assumptions used in Tier II for the sediments and fish tissue approach.

The use of an "intermediate" bioaccumulation factor/fish for Tier II analysis must be compatible with the problem context. For example, if people are eating fish with the potential for high bioaccumulation, this could result in a conclusion that is not protective.

When dealing with "small" "hot spots" the guidance should consider other factors, including sediment mobility (potential to be transported off site) or other relevant processes. The need for considering other processes will become even more important as the transition is made from answering the question "Is there risk?" to the question "What should we do about it?" Not all "yes" answers to the first question will prompt the same, or even similar, answers to the second question. Nature of contaminant concentration with depth, sediment erosion and deposition

potential, etc. play an important role in projecting what the risks are over the long-term and how those risks should be managed. Consideration of the temporal dimension of risk is missing from the current analysis framework. How will guidance deal with sensitive sub-populations of fish consumers, e.g., pregnant woman or children? Such Guidance should be an integral part of the Assessment Framework document.

Site-specific information on fish ingestion rates should be used in place of state-wide values when such data are available.

The notes reflect issues we raised about spatial scale. This may be one of the most important items and needs to be given more thought by the Science Team. Last year we suggested a few methods for dealing with scales but it appears that was dismissed. A short problem formulation piece be developed on this ASAP so that we can see how the matter is being considered. I also think the current method inappropriately dilutes out ambient conditions when using a site use factor. That too needs further thought.

Foraging area was not considered in the sensitivity analysis. The science team indicated that this was an oversight. It should be noted that foraging area is a sensitive and important parameter in these analyses and is deserving of careful consideration and development within the guidance. Literature reviews (particularly of NMFS and other reports) are an important source of information. Telemetry studies have become more cost effective and should be considered as part of tier 3 considerations.

The use of one BAF for all chlorinated organics isn't a reasonable approach considering the range in chemical properties (e.g., Kow) within this group. At the very least the BAF should be appropriate to the log Kow.

Model validation is an application-specific issue. Just because the Gobas framework was validated for one application doesn't mean that another site-specific application will be "valid' given the specifics of that site and associated data limitations. Requirements for calibration and validation within the tiered framework should be developed.

The science team should consider opportunities for allowing improvements to the modeling approach even within Tier II, e.g., collecting benthic tissue or using data from bioaccumulation tests in place of modeled estimates. The tiered framework should not inhibit making improvements to analyses and modeling.

The team should acknowledge that the sensitivity of the model to input parameters will vary across sites and applications. Care should be taken to not over-generalize.

In the revision to the sensitivity analysis, make it more clear that "key parameters" defined by distributions in the sensitivity analysis represent those for which site-specific information could be collected and not necessarily those contributing most to variability/uncertainty in risk predictions. For example, uncertainty about the toxicity of a chemical might contribute greatly to uncertainty about risk, but toxicity values (i.e., Cancer Slope Factors and Reference Doses) are

being treated as point estimates. Account for correlations among inputs quantitatively where possible.

In developing sampling guidance, keep in mind the interplay between sample size and 95% UCLs. With sample sizes of 2 and 5 that are mentioned in the preliminary documents reviewed by the SSC, 95% UCLs cannot be calculated (sample size of 2) or are likely to be higher than the maximum detected concentration (sample size of 5).

The use of additional data to support the assessment is recommended and guidance should be developed most likely for Tier II). There is so much uncertainty associated with the Gobas Model aspect and the assessment of sediment as a source, that additional supporting data are required to fully interpret the contribution from sediment. What is suggested is standard in some other states with respect to sediment assessment. In particular, once the site boundaries are defined it is customary to place the site data into broader perspective. For EPA Region 5 this involves determining of "ambient conditions"; for Massachusetts this is referred to a Local Conditions assessment. Tier II should require a design of sample collection that would allow for differentiating site conditions from ambient (is the site consistent or is it elevated) and spatial trends. This again goes back to the spatial aspects that are currently missing in the framework. There exists guidance from other jurisdictions on how this should/could be done. Also, the responsible party (municipality, companies etc.) should be able to augment with other lines of evidence geared toward answering the questions regarding sediment contribution. This could be a narrative with a few examples of lines of evidence. This too could occur in either Tiers II or III. Bioaccumulation, pore water, and other bioavailability tests are the most obvious additional lines of evidence analogous to those for Direct Effects assessment. These can be collected at select stations when the sediments are collected. This is as important a consideration as mobilization of sediments and while such work is time consuming and it is better to obtain samples before hand they as part of a single collection strategy within Tier II rather than multiple collections and studies.

During the July 2010 meeting, the terms “BSAF” and “BAF” were used interchangeably in the presentation materials when discussing the bioaccumulation model. In revising the model description(s), clarify which term is actually being used.

Based on document the “Proposed Stochastic Method” dated May6, 2010, the following items should be considered.

1. As proposed, what is allowed to vary is the estimate of the mean fish and/or sediment concentration rather than the full distributions. This is negotiable, and the rationale for using just the error about the estimate of the mean should be better justified. For example, by using the full distribution of the sediment, one can somewhat account for spatial variability and potential hotspots. This would be of more importance in situations where the foraging area of a fish is less than the site area. When the site area is less than the foraging area, this would be a moot point. (Even so, there would have to be a non-trivial reconciliation between spatial heterogeneity in sediment conc., foraging area, and total site area). In the end, this all could be rendered moot by the low sample sizes recommended (n=2 to n=5).

2. We discussed simplifications to Tables 2 and 3, which were hard to follow as initially presented. They can be made much easier.

3. There is discussion of the role of sample size on estimates of the mead/median. You might want to provide quantitative guidance on sample size vs. precision of the estimate of the mean, especially in a sample of fish that may have high natural stochasticity/variability.

4. How sensitive is the analysis to the decision to model foraging range using a uniform distribution? How would a triangular distribution have changed outcomes?

5. We did discuss better ways to present the comparison of modeled vs. measured fish data. Rather than simply compare median model data with median measured data, you could at a minimum present the 5^{th}, 25^{th}, 75^{th}, and 95^{th} percentiles as well.

From the document "Sensitivity Analyses to determine……" document dated June 11, 2010, the following issues need to be considered.

1. Related to comment 1 above, using mean fish values may be OK, given the long exposure durations and averaging times but should be fully justified.

2. A real potential problem is the implications of this sensitivity analysis for Phase II modeling. As presented, tissue contamination and seafood consumption were the largest contributors to overall variation for both cancer and non-cancer risks. Both were approximately equal (42% (tissue) vs 38% (consumption) for cancer risks, 46% (tissue) vs. 42% (consumption) for non-cancer risks). As I understood it, the analysis presented to us was from data throughout CA. For the fish tissue, means were taken from each location, and a mean of the means was calculated. For the Monte-Carlo analysis, the variance of the mean of the means was sampled. My guess is that the variance amongst the means from different sites is larger than the variance about the estimate of the mean within a given site. It is the individual locations, however, where the Phase II Monte-Carlo modeling will be applied. If the variance about the estimate of a mean within a site is smaller than the variance used in the model presented, then the contribution of tissue contaminant concentration to overall variance will be smaller. In that case, the distribution of seafood consumption rate will be of most importance. It could be that the choice of the consumption distribution would be the single driving factor for Phase II risk modeling. That takes control out of the local fish collection, and makes sample size moot. In a worst case scenario, using of a standard concentration of fish may be all that is needed. The bottom line is that the spatial scale used for the sensitivity analysis is very different than the spatial scales that will be used for Phase II modeling. The exercise presented, while interesting, may not be germane to site-specific models.

From the "Proposed approach for the Tier I screening assessment" document dated June 24, 2010, the following issues need to be considered.

1. Since the 'off-ramps' for Tier I and removed the seafood "trump card" by the SSC, it is unclear how one will be able to get off at just a Tier I assessment (see comment below).

2. In a related matter, Tier I was designed to have high sensitivity ("a low chance of 'false negatives'") and yet have a reasonable specificity ("correctly identify low risk sites") to presumably allow for a Tier I exit. Given our recommended changes on Tier I exit strategies, and given the battery of conservative values used for the Tier I model, it would help users to know the sensitivity and specificity of the Tier I assessment.

3. Again, based on comments above, a discussion of the use of the UCL of the estimate of the mean vs. the 95% percentile of the full distribution of sediment conc. should be discussed. There would be the same issues as in comment (1).

4. The sample sizes given in Table 4 (n=2 in Phase I and n=5 in Phase II) are pretty small and may lead to in appropriate assessment of the uncertainty.

The kinetic constraints on achieving equilibrium between sediment and water should preclude modeling of water, but the model biases weren't horrific. This should be looked into further. The agencies performing a Phase II model likely will NOT want to do extensive water sampling, which is harder to do than sediment sampling.